



# **Use of Investigational New Drugs In The Combatant Theater for Force Health Protection Question to the AFEB**

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**OASD(HA)**

**May 11, 2004**



# Question to the AFEB

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**•Question: Request the AFEB review the existing Joint Operational Requirement Documents (JORDs), progress on specific efforts to obtain new indications for existing therapeutics, and acquisition status of biologics (treatments and prophylaxis) against the current prioritized list of biowarfare agents and make recommendations on the current status of requirements and**



# Background

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- **Mar 00, ASD(HA) asks AFEB for recommendations on treatment for 6 biowarfare agents.**
- **Aug 00, AFEB provides recommendation for prophylaxis and treatment of the 6 biowarfare agents.**
- **Aug 01, OASD(HA) provides status brief to AFEB.**
- **May 02, OASD(HA) provides status brief to AFEB and new question to board on JORDs.**



# Summary of Aug 01 Brief

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DoD is seeking advise from experts.

DoD Directive 6200.2, August 2000,  
provides policy, implements laws,  
Executive Order, and FDA regulations.

DoD is working to get contingency IND  
protocols for high threat agents.

DoD is developing Implementation  
guidance.

DoD is working with industry to get label  
indications FDA approved.



# Summary of May 02 Brief

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- The AFEB concurred with a need for a JORD for new indications for existing therapeutics, and acquisition of treatments and prophylaxis against the current prioritized list of biowarfare agents.
- The AFEB chair recommended that DoD consult with CDC on IND protocols for medical countermeasures against bioterrorism agents.



# **Status Since Last AFEB Brief**

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- **1. DoD and CDC coordinate on INDs needed to support DoD. ONGOING = Routine DoD/CDC/FDA interactions.**
- **2. Smallpox Vaccine diluents FDA approved. DoD established a Smallpox vaccination program. VIG and Cidofovir INDs support program.**
- **3. Dr. Winkenwerder and Dr. Russell co-chair a WMD Workgroup for interactions to achieve medical countermeasures for biothreat agents. Established at least 6 sub working group.**



# Status Continued

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- **PB licensed by FDA as Soman Nerve Agent Prophylaxis - Pyridostigmine (SNAPP). ASD(HA) establishes PB policy memo.**
- **ASD(HA) establishes Policy Memo listing those INDs related to Force Health Protection IAW DoDD 6200.2.**
- **CBDP re-organized. Joint Requirements Office (JRO) established. Joint Capabilities Integration and Development System (JCIDS) process approved.**



# Status Continued

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- **USAMRMC establishes IND Steering Group.**
- **ASD(HA) establishes position of CBRN Medical Director.**
- **ASD(HA) establishes CDC Liaison Position (LTC Noah)**
- **ASD(HA) working with JRO to establish ICDs for CBRN Medical Countermeasures. This closes loop from last brief asking for AFEB support for JORD. ICD replaces JORD.**